

**PHARMACEUTICAL CARE IN THE  
MANAGEMENT OF PEOPLE WITH  
TYPE 2 DIABETES MELLITUS:  
A RANDOMIZED CONTROLLED  
TRIAL**

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**FACULTY OF MEDICINE  
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KUALA LUMPUR**

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## **Abstract**

Diabetes mellitus is a lifelong chronic condition that requires continuous healthcare and patient's self-management. Lifestyle modifications and adherence to anti-diabetes medications are the major determinants of therapeutic success in the management of diabetes. The fundamental goal of pharmacy practice today is to provide PC which directly influences effective, rational and safe medication use, leading to better health outcomes. Studies which evaluated the effects of PC in the management of people with diabetes found a statistically significant reduction in HbA<sub>1C</sub> in the intervention group. However, most studies in the literature were conducted in developed countries. Therefore, the present study is warranted to investigate the effects of a pharmaceutical care (PC) model in the management of people with type 2 diabetes in Malaysia.

A total of 241 people with type 2 diabetes were recruited from the Diabetes Clinic of the University Malaya Medical Centre (UMMC) and allocated at random to the control (n=121) or intervention (n=120) group. Participants in the intervention group received pharmaceutical care (PC) from an experienced pharmacist while those in the control group were provided the standard pharmacy service.

A range of clinical outcomes that included fasting blood glucose (FBG), glyclated haemoglobin (HbA<sub>1C</sub>), lipid profile and blood pressure (BP); and non-clinical outcomes (medication adherence, knowledge of participants, quality of life and pharmaceutical care issues) were collected and analysed at baseline and then at 4, 8 and 12 months after the initiation of intervention.

At baseline, there was no significant difference in demographic and clinical characteristics of the participants between the control and intervention groups. Significant reductions in mean (standard deviation, SD) of FBG [9.4 (3.4) mmol/L versus 7.5 (2.3)

mmol/L, HbA<sub>1C</sub> [9.6 (1.3)% versus 8.2 (1.3)%], systolic BP [142.9 (18.4) mmHg versus 134.0 (15.1) mmHg], diastolic BP [79.5 (10.9) mmHg versus 77.0 (9.8) mmHg] were found between the control and intervention group 12 months after the provision of PC. In addition, medication adherence ( $p = 0.001$ ) and knowledge of participants ( $p < 0.001$ ) in the intervention group increased significantly. The control group on the other hand, showed no significant improvement in clinical outcomes.

During the study period, the pharmacist identified 408 PC issues (PCIs) and facilitated 598 PC interventions. Of these 408 PCIs, the pharmacist in this study managed to solve 333 (81.6%). Each drug-related problem (DRP) were linked to at least three root causes that were related and directed to the participants (45.7%) or their caregivers (54.8%).

In conclusion, the provision of the PC model used in this study for the management of type 2 diabetes mellitus (T2DM) has produced positive effects on both clinical and behavioural outcomes of the intervention participants. Therefore, collaborative efforts between pharmacist and other healthcare professionals should be implemented in all healthcare institutions to achieve more effective, rational and safe medication use and hence, better clinical outcomes.

## **Abstrak**

Diabetes mellitus adalah penyakit kronik yang memerlukan penjagaan kesihatan dan pengurusan yang berterusan sepanjang hayat oleh pesakit sendiri. Pengubahsuaian gaya hidup dan pematuhan kepada ubat-ubatan anti-diabetes adalah penentu utama untuk kejayaan terapeutik dalam pengurusan diabetes. Matlamat asas amalan farmasi pada zaman sekarang adalah untuk memberi penjagaan farmaseutikal (PC). Dengan secara langsung, PC yang diberikan akan mempengaruhi keberkesanaan, rasional dan penggunaan ubat-ubatan dengan selamat yang membawa hasil kesihatan yang lebih baik. Namun, kebanyakan hasil kajian dalam kesusteraan hanya dijalankan di negara-negara yang maju. Oleh yang demikian, kajian tersebut diperlukan untuk menyiasat kesan sesuatu model PC dalam pengurusan orang yang menghidapi diabetes jenis 2 di Malaysia.diabetes.

Seramai 241 orang dengan diabetes jenis 2 dipilih dari Klinik Diabetes di Pusat Perubatan Universiti Malaya (PPUM) dan dibahagikan secara rawak ke dalam kumpulan kawalan (n = 121) dan intervensi (n = 120). Peserta-peserta dalam kumpulan intervensi menerima PC daripada seorang ahli farmasi yang berpengalaman, manakala peserta-peserta dalam kumpulan kawalan menerima perkhidmatan farmasi yang biasa.

Pelbagai hasil kajian klinikal termasuk paras glukosa darah semasa puasa (FBG), hemoglobin gliklat (HbA<sub>1C</sub>), profil kolesterol dan tekanan darah (BP); dan hasil kajian bukan klinikal seperti pematuhan ubat, pengetahuan, kualiti hidup dan isu-isu penjagaan farmaseutikal, telah dikumpul dan dianalisis pada permulaan kajian serta pada bulan ke-4, ke-8 dan ke-12 selepas intervensi dimulakan.

Pada permulaan kajian, tidak terdapat sebarang perbezaan yang signifikan dari segi demografi dan ciri-ciri peserta di antara kumpulan kawalan dan intervensi. Namun, terdapat pengurangan yang signifikan ( $p < 0.05$ ) ke atas ukuran purata (deviasi piawai, SD) di antara bacaan permulaan berbanding dengan bacaan akhir pengajian untuk FBG [9.4 (3.4) mmol/L berbanding 7.5 (2.3) mmol/L, HbA<sub>1C</sub> [9.6 (1.3)% berbanding 8.2 (1.3)%], BP sistolik [142.9 (18.4) mmHg berbanding 134.0 (15.1) mmHg], BP diastolik [79.5 (10.9) mmHg berbanding 77.0 (9.8) mmHg] sertapeningkatan yang ketara dalam markah pematuhan kepada ubat-ubatan ( $p = 0.001$ ) dan skor purata pengetahuan peserta mengenai diabetes ( $p < 0.001$ ) diperhatikan dalam kumpulan intervensi. Manakala, kumpulan kawalan tidak menunjukkan sebarang pembaikan dalam hasil klinikalnya.

Dalam tempoh kajian tersebut, ahli farmasi berjaya mengenalpasti 408 isu-isu PC (PCIs) dan mencadangkan sebanyak 598 intervensi PC. Daripada jumlah 408 PCIs ini, ahli farmasi berjaya menyelesaikan 333 (81.6%) isu-isu PC. Setiap masalah yang berkaitan dengan ubat-ubatan (DRP) telah dikaitkan dengan sekurang-kurangnya tiga punca penyebab yang berkenalan dan ditujukan kepada peserta (45.7%) atau penjaga mereka (54.8%).

Kesimpulannya, pemberian sesuatu model PC dalam kajian tersebut untuk pengurusan diabetes mellitus jenis 2 di Malaysia menghasilkan kesan klinikal dan perubahan kelakuan secara positif pada peserta-peserta intervensi. Oleh itu, kerjasama di antara ahli-ahli farmasi dan profesional kesihatan yang lain perlu dilaksanakan di semua institusi kesihatan untuk mencapai hasil klinikal yang lebih berkesan, rasional dan penggunaan ubat-ubatan yang lebih selamat.

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## LIST OF SYMBOLS AND ABBREVIATIONS

$\chi^2$	Pearson chi-square
ACCORD	Action to Control Cardiovascular Risk in Diabetes
ACEi	Angiotensin Converting Enzyme Inhibitor
ADA	American Diabetes Association
ADVANCE	Action in Diabetes and Vascular Disease
AGI	Alpha Glucosidase Inhibitors
ARB	Angiotensin-II-Receptor Blockers
BMI	Body Mass Index
BP	Blood Pressure
CDC	Centers for Disease Control and Prevention
CT	Control trial
CPG	Clinical Practice Guidelines
CV	Cardiovascular
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
DC	Diabetes Care
DCCT	Diabetes Control and Complications Trial
DHL	Diabetes, Hypertension and Hyperlipidaemia
DM	Diabetes Mellitus
DPP-4	Dipeptidyl Peptidase-4
DRP	Drug Related Problems
FBG	Fasting Blood Glucose



FIP	International Pharmaceutical Federation
GLP-1	Glucagon Like Peptide-1
HbA <sub>1C</sub>	Glycated Haemoglobin
HDL	High Density Lipoprotein
IDF	International Diabetes Federation
INT	Intervention
LDL	Low Density Lipoprotein
MALMAS	Malaysian Medication Adherence Scale
MAP	Medication Assistance Program
MMAS-9	Morisky Medication Adherence Scale
NHMS	National Health and Morbidity Survey
OAD	Oral Antidiabetes Agents
PC	Pharmaceutical Care
PCIs	Pharmaceutical Care Issues
PCNE	Pharmaceutical Care Network Europe
PCP	Pharmaceutical Care Program
PDM	Persatuan Diabetes Malaysia
QoL	Quality of Life
RCT	Randomized Controlled Trial
SMBG	Self-Monitoring Blood Glucose
SBP	Systolic Blood Pressure
SD	Standard Deviation
SU	Sulphonylurea

T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TC	Total Cholesterol
TG	Triglycerides
TZD	Thiazolidinediones
UC	Usual Care
UK	United Kingdom
UKPDS	United Kingdom Prospective Diabetes Study
UMMC	University Malaya Medical Centre
US	United States
WHO	World Health Organization